UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF OKLAHOMA

ROBERT KING,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. CIV-23-406-DES

Judge _____

JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, Robert King, by Plaintiff's attorneys, Adler Markoff & Associates and Johnson Becker, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and have their principal places of business in states other than the state in which Plaintiff resides, which is Oklahoma.

2. This Court has personal jurisdiction over Defendant, consistent with the United States Constitution and 12 Okla. Stat. Ann. § 2004(F) (Oklahoma's "long arm" statute), as Plaintiff's claims arise out of Defendant's transaction of business and the tortious acts within the State of Oklahoma, and by virtue of Defendant's substantial, continuous, and systematic contacts with the State of Oklahoma unrelated to Plaintiff's claims.

NATURE OF THE CASE

3. This is an action for damages suffered by Plaintiff, Robert King, who was severely injured as a result of Plaintiff's use of Trulicity, an injectable prescription medication that is used to control blood sugar in adults with type 2 diabetes and to reduce cardiovascular risk in patients with type 2 diabetes.

4. Trulicity is also known as dulaglutide. Trulicity works by stimulating insulin production and reducing glucose production in the liver helping to lower blood sugar levels.

5. Trulicity belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

6. Defendant acknowledges that gastrointestinal events are well known side effects of the GLP-1RA class of drugs.[1] However, Defendant has downplayed the severity of the gastrointestinal events caused by Trulicity, never, for example, warning of the risk of ileus, intestinal obstruction, and their sequelae.

7. Ileus is "a temporary lack of the normal muscle contractions of the intestines."[2] Muscles in the intestines normally contract and relax, causing a wave-like motion called peristalsis, which moves food through the intestines. When ileus occurs, this peristalsis is slowed or stopped, preventing food, gas, and liquids from passing through the digestive tract. This causes pain, cramps, abdominal bloating, nausea, vomiting, severe constipation, and loss of appetite. When a person suffering from ileus eats solid food, a backlog of food particles may cause a partial or total

[1] *See, e.g.*, CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (last visited on 9/26/23); *News Release: Trulicity (dulaglutide) is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease,* Eli Lilly (Feb. 21, 2020), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-first-and-only-type-2-diabetes-medicine ("The most common adverse events leading to the discontinuation of Trulicity were gastrointestinal events.").

[2] Parswa Ansari, *Ileus*, Merck Manual (April 2023), available at https://www.merckmanuals.com/home/digestive-disorders/gastrointestinal-emergencies/ (last visited on 10/16/23).

obstruction of the intestines.[3]

8. Paralytic ileus, also known as a pseudo-obstruction, is the most severe form of ileus and occurs when nerves in the intestinal walls do not work as they should, and peristalsis is temporarily paralyzed. Paralytic ileus is a functional problem in which the muscles and nerves mimic an intestinal obstruction, even when there is no actual obstruction in the intestines; this causes food to be trapped in the intestines.[4]

9. Intestinal obstruction, which may also arise from ileus, refers to a partial or total blockage of the intestine, preventing food, liquids or gas from passing through.[5] This may cause the intestine to rupture, leaking harmful contents into the abdominal cavity, or "the blocked parts of the intestine can die, leading to serious problems."[6] Similar to ileus, symptoms of intestinal obstruction include cramps, abdominal pain, loss of appetite, constipation, vomiting, inability to have a bowel movement or pass gas, and swelling of the abdomen.[7] But in contrast to ileus, which refers to the slowing or stopping of peristalsis, generally from muscle or nerve problems, intestinal obstruction refers to the physical blockage of the digestive tract.[8]

PARTY PLAINTIFF

10. Plaintiff, Robert King, is a citizen of the United States, and is a resident of the State

[3] Jayne Leonard, Youssef (Joe) Soliman, *What is Ileus?*, Medical News Today (March 13, 2023), available at https://www.medicalnewstoday.com/articles/322149 (last visited on 10/16/23).
[4] Cleveland Clinic, *Paralytic Ileus* (Oct. 8, 2021), available at https://my.clevelandclinic.org/health/diseases/21853-paralytic-ileus (last visited on 10/16/23); *see also* Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/diagnosis-treatment/drc-20351465?p=1 (last visited on 10/16/23).
[5] Kristeen Moore, E. Mimi Arquilla, *Bowel Obstruction and Blockage*, Healthline (March 15, 2023), available at https://www.healthline.com/health/intestinal-obstruction (last visited on 10/16/23).
[6] Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/symptoms-causes/syc-20351460 (last visited on 10/16/23); *see also* Kristeen Moore, E. Mimi Arquilla, *Bowel Obstruction and Blockage*, Healthline (March 15, 2023), available at https://www.healthline.com/health/intestinal-obstruction (last visited on 10/16/23).
[7] Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/symptoms-causes/syc-20351460 (last visited on 10/16/23).
[8] Jayne Leonard, Youssef (Joe) Soliman, *What is Ileus?*, Medical News Today (March 13, 2023), available at https://www.medicalnewstoday.com/articles/322149 (last visited on 10/16/23).

of Oklahoma.

11. Plaintiff is 70 years old.

12. Upon information and belief, Plaintiff used Trulicity from January 5, 2022 to January 29, 2022.

13. Plaintiff's physician(s) Rebecca Kriegsman ("prescribing physician(s)") prescribed the Trulicity that was used by Plaintiff.

14. As a result of using Defendant's Trulicity, Plaintiff was caused to suffer from ileus and/or intestinal obstruction, and their sequelae and, as a result, sustained severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

15. As a result of using Defendant's Trulicity, Plaintiff was caused to suffer from ileus and/or intestinal obstruction, and their sequelae which resulted in hospitalization.

PARTY DEFENDANT

16. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with a principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

17. Eli Lilly designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed Trulicity and is identified on its label.[9]

FACTUAL BACKGROUND

A. FDA's Approval of Trulicity

18. On September 18, 2014, the FDA approved Eli Lilly's Biologics License Application ("BLA") for dulaglutide "as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus" to be marketed as Trulicity in "single dose pre-filled syringes and pre-filled pens." As initially approved, the recommended dose for Trulicity was

[9] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).

1.5 mg per week.[10]

19. On April 19, 2019, Eli Lilly submitted supplemental BLA 125469/S-033, requesting approval to expand its marketing of Trulicity by adding an indication for reduction of major cardiovascular events in adults with type 2 diabetes. On February 21, 2020, the FDA approved the request.[11]

20. On November 4, 2019, Eli Lilly submitted BLA 125469/S-036, seeking approval for higher doses (3 mg per week and 4.5 per week) of Trulicity. On September 3, 2020, the FDA approved that request.[12]

21. On May 17, 2022, Eli Lilly submitted BLA 125469/S-051, seeking to add an indication for a new patient population: "pediatric patients 10 years of age and older with type 2 diabetes mellitus." On November 17, 2022, the FDA approved the drug for pediatric use.[13]

22. At all times, Trulicity's label has indicated that Trulicity delays gastric emptying and that the delay in gastric emptying "diminishes with subsequent doses." However, Trulicity's label has never warned that Trulicity can cause ileus, intestinal obstruction, and their sequelae.

B. Eli Lilly's Marketing and Promotion of Trulicity

23. Trulicity has been the top earning product for Eli Lilly for the past several years, with the drug bringing in more than $5.6 billion in revenue in 2022 in the United States alone. The demand for Trulicity is largely driven by Eli Lilly's advertising, which costs the company more than $1 billion annually. Indeed, Eli Lilly advertises Trulicity through its websites, press releases,

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[10] FDA Approval Letter for BLA 125469/0 (Sept. 18, 2014), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/125469Orig1s000ltr.pdf (last visited Nov. 8, 2023).

[11] FDA Approval Letter for BLA 125469/S-033 (Feb. 21, 2020), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/125469Orig1s033ltr.pdf (last visited Nov. 8, 2023).

[12] *See News Release: FDA approves additional doses of Trulicity (dulaglutide) for the treatment of type 2 diabetes,* Eli Lilly (Sept. 3, 2020) available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-additional-doses-trulicityr-dulaglutide-treatment (last visited Nov.15, 2023).

[13] FDA Approval Letter for BLA 125469/S-051 (Nov. 17, 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/125469Orig1s051ltr.pdf (last visited Nov. 15, 2023).

in-person presentations, the drug's label, print materials, social media, and other public outlets. Eli Lilly's advertisements tout the health benefits of Trulicity, without warning of the risk of ileus, intestinal obstruction, or their sequelae.[14]

24. Upon the approval of Trulicity on September 18, 2014, an Eli Lilly spokesperson indicated that Trulicity "has demonstrated proven glycemic control, only has to be taken once weekly, and comes in an easy-to-use pen."[15] Although a press release accompanying Trulicity's approval acknowledged that "nausea," "vomiting" abdominal pain" were among the most common adverse reactions reported with use of Trulicity, the press release did not indicate that those common adverse reactions were symptoms of ileus or intestinal obstruction or warn of the risk of ileus, intestinal obstruction, or their sequelae.[16]

25. Following the FDA's approval of Trulicity in September 2014, Eli Lilly launched its direct-to-consumer ad campaign in 2015, with print and digital ads first appearing in September 2015 and the first Trulicity television ad launching on October 19, 2015.[17]

26. On November 5, 2018, in a press release announcing Trulicity's "superiority in reduction of cardiovascular events," as shown by an internal clinical trial, Eli Lilly acknowledged that "[t]he safety profile of Trulicity ... was generally consistent with the GLP-1 receptor agonist class." Although the press release included a section titled "Important Safety Information for Trulicity," the press release did not warn that Trulicity can cause ileus, intestinal obstruction, or

[14] Eli Lilly and Company 2022 Annual Report, available at https://investor.lilly.com/static-files/2f9b7bb1-f955-448d-baa2-c4343d39ee62 (last visited Nov. 15, 2023).
[15] *Lilly's Trulicity (dulaglutide) Now Available in U.S. Pharmacies,* PR Newswire (Nov. 10, 2014), available at https://www.prnewswire.com/news-releases/lillys-trulicity-dulaglutide-now-available-in-us-pharmacies-282138401.html (last visited Nov. 15, 2023).
[16] *News Release: FDA Approves Trulicity (dulaglutide), Lilly's Once-Weekly Therapy for Adults with Type 2 Diabetes,* Eli Lilly (Sept. 18, 2014), available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-trulicitytm-dulaglutide-lillys-once-weekly-therapy (last visited Nov. 15, 2023).
[17] Beth Snyder Bulik, *One year after FDA nod, Eli Lilly's Trulicity launches first consumer campaign,* Fierce Pharma (Oct. 19, 2015) https://www.fiercepharma.com/dtc-advertising/one-year-after-fda-nod-eli-lilly-s-trulicity-launches-first-consumer-campaign (last visited Nov. 15, 2023).

their sequelae.[18]

27. In a February 21, 2020, press release announcing Trulicity's new indication for reduction of cardiovascular risk, Eli Lilly touted Trulicity's ability to reduce the risk of major adverse cardiovascular events, including heart attack and stroke, even in adults without established cardiovascular disease.[19] In the press release, Eli Lilly again indicated that "Trulicity's safety profile [is] consistent with the GLP-1 receptor agonist (RA) class," but despite warning of certain risks, the press release did not warn of the risk of ileus, intestinal obstruction, or their sequelae, associated with GLP-1RAs.

28. When announcing the approval of higher weekly doses of Trulicity in September 2020, Eli Lilly's press release indicated that "with the 3.0 and 4.5 [mg] doses available, people with type 2 diabetes who use Trulicity can benefit from additional A1C and weight loss as their condition progresses."[20] Despite touting the off-label use of Trulicity for "weight loss," Eli Lilly did not warn of the associated risk of ileus, intestinal obstruction, or their sequelae.

29. Around this same time, Robert H. Schmerling, MD, Senior Faculty Editor and Editorial Advisory Board Member at Harvard Health Publishing commented that the actors in the tv ads for Trulicity appeared notably thinner than the typical person with type 2 diabetes.[21]

30. In Summer 2021, in conjunction with Eli Lilly's sponsorship of the rescheduled

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[18] *News Release: Trulicity (dulaglutide) demonstrates superiority in reduction of cardiovascular events for broad range of people with type 2 diabetes,* Eli Lilly (Nov. 5, 2018), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-demonstrates-superiority-reduction (last visited Nov. 15, 2023).
[19] *News Release: Trulicity (dulaglutide) is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease,* Eli Lilly (Feb. 21, 2020), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-first-and-only-type-2-diabetes-medicine (last visited Nov. 15, 2023).
[20] *News Release: FDA approves additional doses of Trulicity (dulaglutide) for the treatment of type 2 diabetes,* Eli Lilly (Sept. 3, 2020) available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-additional-doses-trulicityr-dulaglutide-treatment (last visited Nov.15, 2023).
[21] Robert H. Schmerling, MD, *Harvard Health Ad Watch: A feel-good message about a diabetes drug,* Harvard Health Publishing (Sept. 18, 2020), available at https://www.health.harvard.edu/blog/harvard-health-ad-watch-a-feel-good-message-about-a-diabetes-drug-2020091620961 (last visited Nov. 15, 2023).

Summer Olympics, Eli Lilly ran extensive television advertisements for Trulicity featuring Olympic gymnast Laurie Hernandez and her father, who has type 2 diabetes. The advertisement indicates that treatment with Trulicity is the "right choice" for people with type 2 diabetes but does not mention or warn about ileus, intestinal obstruction, or their sequelae.[22]

31. In a similar January 2022 tv ad featuring Olympic figure skater Madison Chock and her mother, Eli Lilly again indicated that Trulicity was the "right choice" for people with type 2 diabetes. However, the ad did not warn that Trulicity can cause ileus, intestinal obstruction, or their sequelae.[23]

32. In January 2022, the FDA determined that Eli Lilly's "10,800 Minutes" Instagram advertisement for Trulicity "ma[de] false or misleading claims and representations about the benefits and risks of Trulicity" and that the advertisement elicits "a misleading impression regarding the safety and effectiveness of Trulicity" that "minimizes the risks associated with the use of Trulicity." In response to a letter from the FDA, Eli Lilly temporarily removed the Trulicity Instagram account.[24] The FDA citation is emblematic of Eli Lilly's willingness to mislead and omit important information, focusing on profit over safety, specifically with respect to Trulicity.

33. That same month, it was reported that Trulicity was the most advertised drug on United States television, with Eli Lilly spending an estimated $36.2 million on national television

[22] *See* Trulicity TV advertisement, available at https://www.youtube.com/watch?v=eVA1vYV980w (last visited Nov. 15, 2023); Beth Snyder Bulik, *Lilly warms up for Olympics with Team USA athletes in ads for Trulicity, Emgality and Verzenio,* Fierce Pharma (July 7, 2021), available at https://www.fiercepharma.com/marketing/lilly-warms-up-for-olympics-team-usa-athletes-ads-for-trulicity-emgality-and-verzenio (last visited Nov. 15, 2023).
[23] *See* Trulicity TV advertisement (Madison Chock), available at https://www.ispot.tv/ad/q3ii/trulicity-shes-got-this-featuring-madison-chock (last visited Nov. 15, 2023).
[24] Fraiser Kansteiner, *FDA chides Eli Lilly for 2nd misleading ad in 2 months, this time for diabetes blockbuster Trulicity,* Fierce Pharma (Jan. 25, 2022), available at https://www.fiercepharma.com/marketing/fda-chides-lilly-for-second-misleading-ad-2-months-time-for-diabetes-med-trulicity (last visited Nov. 15, 2023).

advertisements in January 2022 alone.[25]

34. In another Trulicity tv ad that premiered in February 2022, Eli Lilly boasted that Trulicity "can help you lose up to ten pounds," a use for which Trulicity is not indicated, but did not mention the risk of ileus, intestinal obstruction, or their sequelae.[26]

35. Similarly, Eli Lilly's website used to promote Trulicity (Trulicity.com) states that people taking Trulicity "lost up to 10 lbs," without disclosing the risk of ileus, intestinal obstruction, or their sequelae.[27]

36. By the end of 2022, the market was experiencing shortages of Trulicity due to "high demand" driven by Eli Lilly's advertising.[28]

C. The Medical Literature and Clinical Trials Gave Defendant Notice of Ileus and Intestinal Obstruction and Their Sequelae Being Causally Associated with GLP-1RAs

37. As previously noted, Trulicity (dulaglutide) belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

38. Medications within the GLP-1RA class of drugs mimic the activities of physiologic GLP-1, which is a gut hormone that activates the GLP-1 receptor in the pancreas to stimulate the release of insulin and suppress glucagon.[29]

39. Because the risks of ileus, intestinal obstruction, and their sequelae are common to the entire class of drugs, any published literature regarding the association between ileus, intestinal

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[25] Ben Adams, *Eli Lilly's Trulicity dethrones Dupixent, taking January's TV ad spending crown,* Fierce Pharma (Feb. 4, 2022), available at https://www.fiercepharma.com/marketing/sanofi-regeneron-s-dupixent-de-throned-as-lilly-s-trulicity-takes-crown-january-s-biggest (last visited Nov. 15, 2023).
[26] Trulicity TV advertisement ("Father-Son"), available at https://www.ispot.tv/ad/q4Kl/trulicity-father-son (last visited Nov. 15, 2023).
[27] *See* https://www.trulicity.com/what-is-trulicity#what-is-trulicity.
[28] https://www.fiercepharma.com/manufacturing/after-novos-wegovy-supply-woes-lillys-would-be-obesity-rival-tirzepatide-runs-scarce
[29] Hinnen D, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30(3) Diabetes Spectr., 202–210 (August 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/ (last visited on 9/26/23).

obstruction, and their sequelae and *any* GLP-1RA (such as tirzepatide, exenatide, liraglutide, albiglutide, dulaglutide, lixisenatide, and semaglutide) should have put Defendant on notice of the need to warn patients and prescribing physicians of the risks of ileus, intestinal obstruction, and their sequelae associated with these drugs.

40. In addition to pancreatic effects, the published medical literature shows that GLP-1 slows gastric emptying and intestinal motility. As explained above, slowing of gastrointestinal motility is what causes ileus and can lead to non-mechanical obstruction.

41. As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism concluded that GLP-1 slows gastric emptying.[30]

42. Defendant knew or should have known of the risks of ileus, intestinal obstruction, and their sequelae from the clinical trials, medical literature, and case reports.

43. In 2008, the New England Journal of Medicine noted that "serious complications" reported as adverse events for the GLP-1RA exenatide included "suspected ileus."[31]

44. In 2012, Japan's Pharmaceutical and Food Safety Bureau advised that "[i]ntestinal obstruction may occur" in patients taking the GLP-1RAs exenatide and liraglutide, and as a result "[p]atients should be carefully monitored, and if any abnormalities including severe constipation, abdominal distention, persistent abdominal pain, or vomiting are observed, administration of [the drugs] should be discontinued, and appropriate measures should be taken." The agency further

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[30] Deane AM et al., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95(1) J Clinical Endo Metabolism, 225-221 (January 1, 2010), available at https://academic.oup.com/jcem/article/95/1/215/2835243 (last visited on 9/26/23); American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (last visited on 9/26/23).

[31] Ahmad, et al., *Exenatide and Rare Adverse Events,* 358 New Eng. J. Med. 1969-1972 (May 2008), available at https://www.nejm.org/doi/full/10.1056/nejmc0707137#:~:text=In%20patients%20with%20gastroparesis%2C%20exenatide,in%20patients%20during%20exenatide%20treatment. (last visited Nov. 16, 2023).

reported that in the previous 1 year and 8 months, three cases of intestinal obstruction had been reported in liraglutide users "for which causality [associated with] the drug could not be ruled out." At least one of those patients was diagnosed with ileus.[32]

45. A 2013 article by a co-author who had participated on Novo Nordisk advisory boards, explained that "[a]cute, intravenous infusion of GLP-1 (in pharmacological doses) slows gastric emptying markedly in both healthy subjects and patients with type 2 diabetes in a dose-dependent manner by mechanisms that include relaxation of the proximal stomach, reduction of antral and duodenal motility, and an increase in pyloric tone, and which involve vagal pathways."[33]

46. In 2013, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) received a "safety communication from the Japanese medicines agency … reporting intestinal obstruction in patients treated with" GLP-1RAs. As a result, PRAC searched EudraVigilance "for intestinal obstruction and related terms" and retrieved 59 cases for the GLP-1RAs exenatide and liraglutide, leading PRAC to recommend appropriate amendments to the product information.[34] Notably, Novo Nordisk manufactures and markets liraglutide under the brand names Saxenda and Victoza.

47. By 2014, animal studies with the GLP-1RA albiglutide demonstrated increased rates of morbidity and mortality in lactating mice, consistent with lactational ileus syndrome.

48. A 2016 trial funded by Novo Nordisk measuring semaglutide and cardiovascular outcomes in patients with type 2 diabetes found more gastrointestinal disorders in the semaglutide

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[32] Pharmaceuticals and Medical Devices Safety Information No. 291, Pharmaceutical and Food Safety Bureau (June 2012), available at https://www.pmda.go.jp/files/000153459.pdf (last visited Nov. 16, 2023).
[33] Marathe C, *Relationships Between Gastric Emptying, Postprandial Glycemia, and Incretin Hormones*, 36(5) Diabetes Care, 1396-1405 (April 13, 2013), available at https://diabetesjournals.org/care/article/36/5/1396/29534/Relationships-Between-Gastric-Emptying (last visited October 26, 2023).
[34] European Medicine Agency, Pharmacovigilance Risk Assessment Committee, minutes of meeting (January 7-10, 2013) available at https://www.ema.europa.eu/en/documents/minutes/minutes-prac-meeting-7-10-january-2013_.pdf (last visited 10/20/23).

group than in the placebo group, including a severe adverse event report of impaired gastric emptying with semaglutide 0.5 mg together with other serious gastrointestinal adverse events such as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.[35]

49. Two subjects in a semaglutide trial pool by Novo Nordisk reported moderate adverse events of impaired gastric emptying and both subjects permanently discontinued treatment due to the adverse events. Three subjects also reported mild adverse events of impaired gastric emptying in the semaglutide run-in period of trial 4376.

50. A study published in 2017 evaluated the effect of GLP-1RAs on gastrointestinal tract motility and residue rates and explained that "GLP-1 suppresses gastric emptying by inhibiting peristalsis of the stomach while increasing tonic contraction of the pyloric region." The study authors concluded that the GLP-1RA drug liraglutide "exhibited gastric-emptying delaying effects" and "the drug also inhibited duodenal and small bowel movements at the same time."[36]

51. Another study in 2017 reviewed the survey results from 10,987 patients and 851 physicians and found that "GI-related issues were the top two patient-reported reasons for GLP-1RA discontinuation in the past 6 months, with 'Made me feel sick' as the most frequently reported reason (64.4%), followed by 'Made me throw up' (45.4%)."[37] As explained above, these are symptoms of ileus and intestinal obstruction.

52. A 2019 study of the GLP-1RA drug dulaglutide identified adverse events for

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[35] Marso, SP, et al., Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes, N. Eng. J. Med. 375:1834-1844 (November 2016), available at https://www.nejm.org/doi/10.1056/NEJMoa1607141 (visited on 10/19/23).

[36] Nakatani Y et al., *Effect of GLP-1 receptor agonist on gastrointestinal tract motility and residue rates as evaluated by capsule endoscopy*, 43(5) Diabetes & Metabolism, 430-37 (October 2017), available at https://www.sciencedirect.com/science/article/pii/S1262363617301076 (last visited on 10/25/23).

[37] Sikirica M et al., *Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes*, 10 Diabetes Metab. Syndr. Obes., 403-412 (September 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5630073/

impaired gastric emptying.

53. In May 2020, the Journal of the Endocrine Society reported a case of a 52-year-old male, with no history of abdominal surgeries, who presented with a partial bowel obstruction that progressed to a full obstruction requiring life-threatening surgical intervention. The patient had begun taking Trulicity (dulaglutide) three weeks prior to hospital admission. The authors noted that "[d]ulaglutide (Trulicity) is associated with small bowel obstruction" but that "the actual mechanism [of] Trulicity causing the small bowel obstruction is unknown." The authors further reported that "[a] total of 8 cases" of bowel obstruction in Trulicity users "were reported in 2017 with a majority of them requiring surgical intervention." In the subject patient, the authors concluded that because "[a]ll the other cause[s] of small bowel obstructions had been ruled out[,] ... Trulicity was the culprit of this unfortunate case."[38]

54. In a September 2020 article funded and reviewed by Novo Nordisk, scientists affiliated with Novo Nordisk reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes. More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1.5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that "[f]or patients reporting severe adverse gastrointestinal reactions, it is advised to monitor renal function when

[38] Gandhi, et al., *Dulaglutide Commonly Known as Trulicity; An Anti-Diabetic Medication Causing Small Bowel Obstruction,* 4 J. Endocrine Soc. A309 (May 2020), available at https://academic.oup.com/jes/article/4/Supplement_1/MON-681/5832661 (last visited Nov. 16, 2023).

initiating or escalating doses of oral semaglutide." For patients with other comorbidities, the study warned that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs." The study further identified as one "key clinical take-home point" that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs."[39]

55. A July 2021 article funded and reviewed by Novo Nordisk considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that "gastrointestinal disturbances" were "well-known" side effects associated with semaglutide use. When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus up to 8% on the placebo group), vomiting in up to 11.5% of patients (versus up to 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus up to 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for GI-related adverse events, with some trials experiencing 100% discontinuation due to GI-related adverse events. The mean value of GR-related adverse events that led to discontinuation averaged 57.75%. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[40]

56. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[41]

57. An October 2022 study analyzed 5,442 GLP-1RA adverse gastrointestinal events.

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[39] Mosenzon O, Miller EM, & Warren ML, *Oral semaglutide in patients with type 2 diabetes and cardiovascular disease, renal impairment, or other comorbidities, and in older patients*, Postgraduate Medicine (2020), 132:sup2, 37-47, available at https://doi.org/10.1080/00325481.2020.1800286 (visited on 9/26/23).

[40] Smits MM & Van Raalte DH (2021), *Safety of Semaglutide*, Front. Endocrinol., 07 July 2021, doi: 10.3389/fendo.2021.645563, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/ (last visited on 9/26/23).

[41] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).

32% were serious, including 40 deaths, 53 life-threatening conditions, and 772 hospitalizations. The primary events were nausea and vomiting. There were also adverse events for impaired gastric emptying.[42]

58. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[43]

59. In February 2023, a longitudinal study of GLP-1RA (dulaglutide) reported adverse events for nausea and vomiting, and one adverse event of impaired gastric emptying.[44]

60. On March 28, 2023, a case study concluded that impaired gastric emptying is "a significant safety concern, especially since it is consistent with the known mechanism of action of the drug."[45]

61. In a May 2023 letter to the editor published in Acta Pharmaceutica Sinica B, the authors commented on GLP-1RAs, including Ozempic, Wegovy, and Rybelsus, and noted "adverse events such as increased risk of intestinal obstruction have been reported in diabetic patients, which is 4.5 times higher than those receiving other glucose control medications" based on a study published in 2020. The authors further noted a study published in 2022 "of 25,617 subjects demonstrated a 3.5-fold increase in the intestinal obstruction rate associated with GLP-1RA treatment."[46]

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[42] Shu, *Gastrointestinal adverse events associated with semaglutide: A pharmacovigilance study based on FDA adverse event reporting system*, Front. Public Health (Oct. 20, 2022). (https://doi.org/10.3389%2Ffpubh.2022.996179).

[43] Mirsha, *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).

[44] Chin, *Safety and effectiveness of dulaglutide 0.75 mg in Japanese patients with type 2 diabetes in real-world clinical practice: 36 month postmarketing observational study*, J Diabetes Investig (Feb. 2023) (https://doi.org/10.1111%2Fjdi.13932).

[45] Klein, Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report, Can J. Anesth (Mar. 28, 2023) (https://doi.org/10.1007/s12630-023-02440-3).

[46] Lu J et al., *A Potentially Serious Adverse Effect of GLP-1 Receptor Agonists*, 13(5) Acta Pharmaceutica Sinica B, 2291-2293 (May 2023), available at https://www.sciencedirect.com/science/article/pii/S2211383523000679 (last visited on 10/19/23); *see also* Faillie JL, et al., *Incretin-Based Drugs and Risk of Intestinal Obstruction Among*

62. In May 2023, the risk of intestinal obstruction was specifically cited in the Lu study, concluding that the use of GLP-1RAs may result in continuous increases in intestinal length, causing the intestines to "become as inelastic and fibrotic as a loose spring." The study indicated that intestinal blockage peaked after using GLP-1RAs for a year and a half, which the authors noted was longer than the duration of most clinical studies involving GLP-1RAs.[47]

63. On June 29, 2023, the American Society of Anesthesiologists ("ASA") warned that patients taking semaglutide and other GLP-1RAs should stop the medication at least a week before elective surgery because these medications "delay gastric (stomach) emptying" and "the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of food into the airways and lungs during general anesthesia and deep sedation." The ASA also warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[48]

64. News sources have identified the potential for serious side effects in users of Ozempic leading to hospitalization.[49] For example, NBC News reported in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said

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Patients with Type 2 Diabetes, Clinical Pharmacology Therapeutics vol. 11, Issue 1 (Jan. 2022), available at https://doi.org/10.1002/cpt.2430 (last visited on 10/19/23) and Gudin B, et al. *Incretin-based drugs and intestinal obstruction: a pharmacovigilance study*, 75(6) Therapies 641-47 (November-December 2020).

[47] Lu, J, et al., *A Potentially Serious Adverse Effect of GLP-1 Receptor Agonists*, 13(5) Acta Pharmaceutica Sinica B, 2291-2293 (May 2023), available at https://www.sciencedirect.com/science/article/pii/S2211383523000679 (last visited on 10/19/23).

[48] American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (last visited on 9/26/23).

[49] Penny Min, *Ozempic May Cause Potential Hospitalizations*, healthnews (June 26, 2023), available at https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/ (last visited on 9/26/23); Elizabeth Laura Nelson, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors*, Best Life (April 3, 2023), available at https://bestlifeonline.com/ozempic-side-effects-news/ (last visited on 9/26/23); Cara Shultz, *Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients*, People (July 26, 2023), available at https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833 (last visited on 9/26/23); CBS News Philadelphia, *Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn* (July 23, 2023), available at https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/ (last visited on 9/26/23).

that five weeks into taking the medication she found herself unable to move off the bathroom floor because she had "vomited so much that [she] didn't have the energy to get up."[50]

65. A July 25, 2023 article in Rolling Stone magazine—"*Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell'*"—discussed the severe gastrointestinal effects of GLP-1RAs. In a statement to Rolling Stone, Novo Nordisk acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo Nordisk further stated that while "GLP-1 RAs are known to cause a delay in gastric emptying, … [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo Nordisk did not claim to have warned consumers about ileus, intestinal obstruction, and their sequelae, or other severe GI issues.[51]

66. On July 25, 2023, CNN Health reported that patients taking GLP-1RAs are experiencing severe gastrointestinal reactions. One patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[52]

67. On July 26, 2023, a New York hospital published an article to its online health blog section noting that GLP-1RAs can delay or decrease the contraction of muscles that mix and propel contents in the gastrointestinal tract leading to delayed gastric emptying. One concern raised was that doctors often misdiagnose the patients' symptoms, meaning it may take a long time for

[50] Bendix A, Lovelace B Jr., *What it's like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds*, NBC News (Jan. 29, 2023), available at https://www.nbcnews.com/health/health-news/ozempic-wegovy-diabetes-weight-loss-side-effects-rcna66493 (last visited on 9/26/23).
[51] CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell'*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (last visited on 9/26/23).
[52] Brenca Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed,* CNN Health (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis (last visited on 9/26/23).

someone to be diagnosed correctly.[53]

68. In an article published on September 29, 2023, Dr. Caroline Apovian, a Professor of Medicine at Harvard Medical School, indicated that "her team had observed ileus in patients who had been prescribed semaglutide well before" Novo Nordisk's September 22, 2023 label change for Ozempic. In the same article, Dr. Dan Azagury, a Medical Director at Stanford University, explained that "ileus is a rare but potentially severe complication. So, we have to inform patients and we have to let them know that if they have these symptoms they need to check in with their physician."[54]

69. In an October 5, 2023, Research Letter published in the Journal of the American Medical Association ("JAMA"), the authors examined gastrointestinal adverse events associated with GLP-1RAs used for weight loss in clinical setting and reported that use of GLP-1RAs compared with use of bupropion-naltrexone was associated with increased risk of pancreatitis, gastroparesis, and bowel obstruction. The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of intestinal obstruction.[55]

70. Also on October 5, 2023, a medical journal reported a case of Mounjaro (tirzepatide) induced ileus. The authors concluded that the case "highlights the dangers of lack of ... monitoring of Mounjaro," especially in "patients who may be more susceptible to the gastrointestinal side effects of Mounjaro," and noted the need to "rais[e] awareness of potential

[53] *Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines*, Montefiore Health Blog article (released July 26, 2023), available at https://www.montefiorenyack.org/health-blog/what-you-need-know-about-gastroparesis (last visited on 9/26/2023).
[54] Mammoser G, *Ozempic Label Updated to Include Blocked Intestines as Potential Side Effect*, healthline (September 29, 2023), https://www.healthline.com/health-news/fda-updates-ozempic-label-to-include-blocked-intestines-as-potential-side-effect (last visited 10/20/23).
[55] Mohit Sodhi, et al., *Risk of Gastrointestinal Adverse Events Associated with Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss*, JAMA (published online October 5, 2023), available at https://jamanetwork.com/journals/jama/fullarticle/2810542 (last visited 10/19/23).

side effects" of the drug "and their severity."[56]

71. The medical literature listed above is not a comprehensive list, and there are additional case reports indicating that GLP-1RAs can cause ileus, intestinal obstruction, and their sequelae.

72. Defendant knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing ileus, intestinal obstruction and their sequelae, but they ignored the causal association. Defendant's actual and constructive knowledge derived from their clinical studies, case reports, medical literature, including the medical literature and case reports referenced above in this Complaint.

73. On information and belief, Defendant not only knew or should have known that their GLP-1RAs cause delayed gastric emptying and inhibit intestinal motility, resulting in risks of ileus, intestinal obstruction, and their sequelae, but they may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that long-acting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[57]

D. Eli Lilly Failed to Warn of the Risk of Ileus and Intestinal Obstruction From Trulicity

74. The Prescribing Information for Trulicity (the "label") discloses "Warnings and

[56] Kamini Rao et al., *Mounjaro: A Side Effect,* 7 J. Endocrine Soc. A69-70 (Oct.-Nov. 2023), available at https://academic.oup.com/jes/article/7/Supplement_1/bvad114.128/7290694 (last visited Nov. 16, 2023).
[57] Jensterle M et al., *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) Diabetes Obes. Metab. 975-984 (April 2023), available at https://dom-pubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944 (last visited on 9/26/23).

Precautions" and "Adverse Reactions" but does not warn that Trulicity can cause ileus or intestinal obstruction.[58]

75. The Trulicity label lists nausea, vomiting, diarrhea, abdominal pain, and decreased appetite as the most common adverse reactions reported in Trulicity patients, but it does not include these adverse reactions in its "Warnings and Precautions" section, nor does it warn that these adverse reactions may be symptoms of ileus and intestinal obstruction. While the Warnings and Precautions section indicates that "Use of TRULICITY may be associated with gastrointestinal adverse reactions, sometime severe," the warning is lacking in urgency and specificity.[59]

76. Instead of properly disclosing gastrointestinal risks, the label for Trulicity encourages prescribing physicians and patients to ignore the signs of ileus and intestinal obstruction and continue therapy with Trulicity because the Drug Interactions and Clinical Pharmacology sections of the label state that the delayed gastric emptying caused by Trulicity "is largest after the first dose and diminishes with subsequent doses."[60]

77. Similarly, Eli Lilly's main promotional website for Trulicity (trulicity.com) includes a variety of information about the benefits of Trulicity relating to blood sugar, cardiovascular health, and weight loss, and includes a section about "Side Effects" and a sidebar containing a "SAFETY SUMMARY WITH WARNINGS." However, Eli Lilly does not disclose the risks of ileus, intestinal obstruction, or their sequelae within either the "Side Effects" or "SAFETY SUMMARY WITH WARNINGS" sections of the website.[61]

78. Nothing in the label for Trulicity has ever disclosed ileus or intestinal obstruction

[58] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).
[59] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).
[60] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).
[61] *See* Trulicity.com (last visited Nov. 15, 2023).

as a ***risk*** of taking Trulicity.

79. None of Eli Lilly's additional advertising or promotional materials warned prescription providers or the general public of the risks of ileus, intestinal obstruction, and their sequelae.

80. Eli Lilly knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing ileus, intestinal obstruction, and their sequelae. Eli Lilly's actual and constructive knowledge derived from its clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced in this Complaint.

81. Upon information and belief, Eli Lilly ignored the causal association between the use of GLP-1RAs and the risk of developing ileus, intestinal obstruction, and their sequelae.

82. Eli Lilly's failure to disclose information that it possessed regarding the causal association between the use of GLP-1RAs and the risk of developing ileus, intestinal obstruction, and their sequelae, rendered the warnings for Trulicity inadequate.

83. On information and belief, as a result of Eli Lilly's inadequate warnings, the medical community at large, and Plaintiff's prescribing physician(s) in particular, were not aware that Trulicity can cause ileus, intestinal obstruction, and their sequelae, nor were they aware that "common adverse reactions" listed on the label might be sequelae of ileus and intestinal obstruction.

84. On information and belief, had Eli Lilly adequately warned Plaintiff's prescribing physician(s) that Trulicity is causally associated with ileus, intestinal obstruction, and their sequelae, then the physicians' prescribing decisions would have changed by not prescribing Trulicity, or by monitoring Plaintiff's health for symptoms of ileus and intestinal obstruction and discontinuing Trulicity when the symptoms first started.

85. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from ileus, intestinal obstruction, and their sequelae, which resulted in severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

FIRST CAUSE OF ACTION
(NEGLIGENCE – FAILURE TO WARN)

86. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

87. Producers, manufacturers, distributors, lessors, and sellers of a product have a duty to exercise all reasonable care when designing, researching, testing, producing, manufacturing, distributing, leasing, advertising, marketing, and selling their products.

88. At all times mentioned herein, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Trulicity that was used by Plaintiff.

89. Trulicity was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendant.

90. At all relevant times, and at the times Trulicity left Defendant's control, Defendant knew or should have known that Trulicity was unreasonably dangerous because it did not adequately warn of the risk of ileus, intestinal obstruction, and their sequelae, especially when used in the form and manner as provided by Defendant.

91. Despite the fact that Defendant knew or should have known that Trulicity caused

unreasonably dangerous injuries, Defendant continued to market, distribute, and/or sell Trulicity to consumers, including Plaintiff, without adequate warnings.

92. Despite the fact that Defendant knew or should have known that Trulicity caused unreasonably dangerous injuries, Defendant continued to market Trulicity to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

93. Defendant knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of its failure to provide adequate warnings, as set forth herein.

94. At all relevant times, given its increased safety risks, Trulicity was not fit for the ordinary purpose for which it was intended.

95. At all relevant times, given its increased safety risks, Trulicity did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

96. Defendant had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Trulicity into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as ileus, intestinal obstruction, and their sequelae.

97. At all relevant times, Plaintiff was using Trulicity for the purposes and in a manner normally intended.

98. The Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate warnings or instructions, as Defendant knew or should have known that this product created a risk of serious and dangerous injuries, including ileus, intestinal obstruction, and their sequelae, as well as other

severe and personal injuries which are permanent and lasting in nature, and Defendant failed to adequately warn of said risk.

99. The Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendant knew or should have known of the risks of serious side effects, including ileus, intestinal obstruction, and their sequelae, as well as other severe and permanent health consequences from Trulicity, it failed to provide adequate warnings to users and/or prescribers of the product, and continued to improperly advertise, market and/or promote its product, Trulicity.

100. The label for Trulicity was inadequate because it did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Trulicity, including the increased risk of ileus, intestinal obstruction, and their sequelae.

101. The label for Trulicity was inadequate because it did not warn and/or adequately warn that Trulicity had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae.

102. The label for Trulicity was inadequate because it did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Trulicity.

103. The label for Trulicity was inadequate because it did not warn and/or adequately warn of the severity and duration of adverse effects, as the warning given did not accurately reflect the symptoms or severity of the side effects.

104. Communications made by Defendant to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendant failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Trulicity, including the increased

risk of ileus, intestinal obstruction, and their sequelae.

105. Communications made by Defendant to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendant failed to warn and/or adequately warn that Trulicity had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae.

106. Plaintiff had no way to determine the truth behind the inadequacies of Defendant's warnings as identified herein, and Plaintiff's reliance upon Defendant's warnings was reasonable.

107. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendant's warnings as identified herein, and his/her/their reliance upon Defendant's warnings was reasonable.

108. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of ileus, intestinal obstruction, and their sequelae, which are causally associated with Trulicity, then the prescribing physician(s) would not have prescribed Trulicity and/or would have provided Plaintiff with adequate warnings regarding the dangers of Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Trulicity.

109. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Trulicity had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, the prescribing physician(s) would not have prescribed Trulicity and/or would have provided Plaintiff with adequate warning regarding the lack of sufficient and/or adequate testing of Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Trulicity.

110. If Plaintiff had been warned of the increased risks of ileus, intestinal obstruction, and their sequelae, which are causally associated with Trulicity, then Plaintiff would not have used

Trulicity and/or suffered from ileus, intestinal obstruction, and their sequelae.

111. If Plaintiff had been warned that Trulicity had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, then Plaintiff would not have used Trulicity and/or suffered ileus, intestinal obstruction, and their sequelae.

112. If Plaintiff had been warned of the increased risks of ileus, intestinal obstruction, and their sequelae, which is causally associated with Trulicity, then Plaintiff would have informed Plaintiff's prescribers that Plaintiff did not want to take Trulicity.

113. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Trulicity due to the risks of ileus, intestinal obstruction, and their sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Trulicity.

114. By reason of the foregoing, Defendant has become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of an unreasonably dangerous product, Trulicity.

115. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendant is therefore liable for the injuries sustained by Plaintiff.

116. Defendant's inadequate warning for Trulicity was an act that amounted to willful, wanton, and/or reckless conduct by Defendant.

117. Said inadequate warning for Defendant's drug Trulicity was a substantial factor in causing Plaintiff's injuries.

118. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including ileus, intestinal obstruction, and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

119. As a result of the foregoing acts and omissions Plaintiff did incur medical, health, incidental, and related expenses, and requires and/or will require more health care and services. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SECOND CAUSE OF ACTION
(STRICT LIABILITY – FAILURE TO WARN)

120. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

121. Producers, manufacturers, distributors, lessors, and sellers of a product have a duty to exercise all reasonable care when designing, researching, testing, producing, manufacturing, distributing, leasing, advertising, marketing, and selling their products.

122. At all times mentioned herein, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Trulicity that was used by Plaintiff.

123. Trulicity was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendant.

124. At all relevant times, and at the times Trulicity left Defendant's control, Defendant knew or should have known that Trulicity was unreasonably dangerous because it did not adequately warn of the risk of ileus, intestinal obstruction, and their sequelae, especially when used in the form and manner as provided by Defendant.

125. Despite the fact that Defendant knew or should have known that Trulicity caused unreasonably dangerous injuries, Defendant continued to market, distribute, and/or sell Trulicity to consumers, including Plaintiff, without adequate warnings.

126. Despite the fact that Defendant knew or should have known that Trulicity caused unreasonably dangerous injuries, Defendant continued to market Trulicity to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

127. Defendant knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of their failure to provide adequate warnings, as set forth herein.

128. At all relevant times, given its increased safety risks, Trulicity was not fit for the ordinary purpose for which it was intended.

129. At all relevant times, given its increased safety risks, Trulicity did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

130. Defendant had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Trulicity into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as ileus, intestinal obstruction, and their sequelae.

131. At all relevant times, Plaintiff was using Trulicity for the purposes and in a manner

normally intended—namely, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

132. The Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate warnings or instructions, as Defendant knew or should have known that the product created a risk of serious and dangerous injuries, including ileus, intestinal obstruction, and their sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendant failed to adequately warn of said risk.

133. The Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendant knew or should have known of the risks of serious side effects, including ileus, intestinal obstruction, and their sequelae, as well as other severe and permanent health consequences from Trulicity, it failed to provide adequate warnings to users and/or prescribers of the product, and continued to improperly advertise, market and/or promote its product, Trulicity.

134. The label for Trulicity was inadequate because it did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Trulicity, including the increased risk of ileus, intestinal obstruction, and their sequelae.

135. The label for Trulicity was inadequate because it did not warn and/or adequately warn that Trulicity had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae.

136. The label for Trulicity was inadequate because it did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Trulicity.

137. The label for Trulicity was inadequate because it did not warn and/or adequately warn of the severity and duration of adverse effects, as the warning given did not accurately reflect the symptoms or severity of the side effects.

138. Communications made by Defendant to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendant failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Trulicity, including the increased risk of ileus, intestinal obstruction, and their sequelae.

139. Communications made by Defendant to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendant failed to warn and/or adequately warn that Trulicity had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae.

140. Defendant had a continuous duty to warn Plaintiff's prescribing physician(s) of the potential danger posed by Trulicity, including ileus, intestinal obstruction, and their sequelae.

141. Plaintiff had no way to determine the truth behind the inadequacies of Defendant's warnings as identified herein, and Plaintiff's reliance upon Defendant's warnings was reasonable.

142. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendant's warnings as identified herein, and his/her/their reliance upon Defendant's warnings was reasonable.

143. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of ileus, intestinal obstruction, and their sequelae, which are causally associated with Trulicity, then the prescribing physician would not have prescribed Trulicity and/or would have provided Plaintiff with adequate warning regarding the dangers of Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Trulicity.

144. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Trulicity had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, the prescribing physician would not have prescribed Trulicity and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Trulicity.

145. If Plaintiff had been warned of the increased risks of ileus, intestinal obstruction, and their sequelae, which are causally associated with Trulicity, then Plaintiff would not have used Trulicity and/or suffered from ileus, intestinal obstruction, and their sequelae.

146. If Plaintiff had been warned that Trulicity had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, then Plaintiff would not have used Trulicity and/or suffered ileus, intestinal obstruction, and their sequelae.

147. If Plaintiff had been warned of the increased risks of ileus, intestinal obstruction, and their sequelae, which is causally associated with Trulicity, then Plaintiff would have informed Plaintiff's prescribers that Plaintiff did not want to take Trulicity.

148. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Trulicity due to the risks of ileus, intestinal obstruction, and their sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Trulicity.

149. By reason of the foregoing, Defendant has become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of an unreasonably dangerous product, Trulicity.

150. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendant is therefore liable for the injuries sustained by Plaintiff.

151. Defendant's inadequate warnings for Trulicity was an act that amounted to willful, wanton, and/or reckless conduct by Defendant.

152. Said inadequate warnings for Defendant's drug Trulicity was a substantial factor in causing Plaintiff's injuries.

153. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including ileus, intestinal obstruction, and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

154. As a result of the foregoing acts and omissions Plaintiff did incur medical, health, incidental, and related expenses, and requires and/or will require more health care and services. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

THIRD CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY UNDER – 12A Okl. Stat. Ann. § 2-313)

155. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

156. At all relevant times, Defendant designed, researched, manufactured, tested,

advertised, promoted, marketed, sold, distributed, and/or have acquired the Defendant who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Trulicity, which was used by Plaintiff as hereinabove described.

157. At all relevant times, Defendant expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that Trulicity was safe as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

158. The aforementioned express warranties were made to Plaintiff and Plaintiff's prescribing physician(s) by way of Trulicity label, website, advertisements, promotional materials, and through other statements.

159. As a result of Defendant's express warranties, Plaintiff's prescribing physician(s) were induced to prescribe Trulicity to Plaintiff, and Plaintiff was induced to use Trulicity.

160. At all relevant times, Defendant reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Trulicity based upon its express warranties.

161. At all relevant times, Defendant reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Trulicity based upon its express warranties.

162. At all relevant times, Defendant knew or should have known Trulicity was unreasonably dangerous because of the increased risk of ileus, intestinal obstruction, and their sequelae, especially when the drug was used in the form and manner as provided by Defendant.

163. At all relevant times, Defendant knew or should have known that Trulicity had not been sufficiently and/or adequately tested for safety.

164. The unreasonably dangerous characteristics of Trulicity were beyond that which

would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drug's characteristics.

165. The unreasonably dangerous characteristics of Trulicity were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drug's characteristics.

166. At the time Trulicity left Defendant's control, Trulicity did not conform to Defendant's express warranties because Trulicity was not safe to use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, in that the drug was causally associated with increased risks of ileus, intestinal obstruction, and their sequelae.

167. The express warranties made by Defendant regarding the safety of Trulicity were made with the intent to induce Plaintiff to use the product and/or Plaintiff's prescribing physician(s) to prescribe this product.

168. Defendant knew and/or should have known that by making the express warranties to Plaintiff and/or Plaintiff's prescribing physician(s), it would be the natural tendency of Plaintiff to use Trulicity and/or the natural tendency of Plaintiff's prescribing physician(s) to prescribe Trulicity.

169. Plaintiff and Plaintiff's prescribing physician(s), as well as members of the medical community, relied on the express warranties of Defendant identified herein.

170. Had Defendant not made these express warranties, Plaintiff would not have used Trulicity, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Trulicity.

171. Plaintiff's injuries and damages were directly caused by Defendant's breach of the aforementioned express warranties.

172. Plaintiff's injuries and damages arose from a reasonably anticipated use of this product by Plaintiff.

173. Accordingly, Defendant is liable as a result of its breach of express warranties to Plaintiff.

174. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including ileus, intestinal obstruction, and their sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

175. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendant's drug, Trulicity.

176. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

FOURTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY UNDER 12A Okla. Stat. Ann. §2-134)

177. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

178. At all relevant times, Defendant designed, researched, manufactured, tested,

advertised, promoted, marketed, sold, and distributed the Trulicity drug used by Plaintiff.

179. Trulicity was expected to and did reach the usual consumers, handlers, and persons encountering said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant.

180. At all relevant times, Defendant impliedly warranted to Plaintiff, Plaintiff's prescribing physician(s), and the medical community that Trulicity was of merchantable quality and safe and fit for its ordinary purposes.

181. At all relevant times, Defendant knew or should have known that Trulicity was unreasonably dangerous because of the increased risk of ileus, intestinal obstruction, and their sequelae, especially when the drug was used in the form and manner as provided by Defendant.

182. At all relevant times, Defendant knew or should have known that Trulicity had not been sufficiently and/or adequately tested for safety.

183. At the time Trulicity left Defendant's control, Trulicity did not confirm to Defendant's implied warranty and was unfit for its ordinary purposes because Defendant failed to provide adequate warnings of the drug's causal association with increased risk of ileus, intestinal obstruction, and their sequelae.

184. At all relevant times, Defendant reasonably anticipated and expected that prescribing physician(s), such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Trulicity for use by their patients to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk, and/or to promote weight loss.

185. At all relevant times, Defendant reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Trulicity for its ordinary purposes.

186. Despite the fact that Defendant knew or should have known that Trulicity caused

unreasonably dangerous injuries, such as ileus, intestinal obstruction, and their sequelae, Defendant continued to market, distribute, and/or sell Trulicity to consumers, including Plaintiff, without adequate warnings.

187. The unreasonably dangerous characteristics of Trulicity was beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drug's characteristics.

188. The unreasonably dangerous characteristics of Trulicity were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drug's characteristics.

189. Plaintiff reasonably relied on Defendant's implied warranty of merchantability relating Trulicity's safety and efficacy.

190. Plaintiff reasonably relied upon the skill and judgment of Defendant as to whether Trulicity was of merchantable quality and safe and fit for its intended use.

191. Upon information and belief Plaintiff's prescribing physician(s) relied on Defendant's implied warranty of merchantability and fitness for the ordinary use and purpose relating to Trulicity.

192. Upon information and belief Plaintiff's prescribing physician(s), reasonably relied upon the skill and judgment of Defendant as to whether Trulicity was of merchantable quality and safe and fit for the drug's intended use.

193. Had Defendant not made these implied warranties, Plaintiff would not have used Trulicity, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Trulicity, and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Trulicity to allow Plaintiff to

make an informed decision regarding Plaintiff's use of Trulicity.

194. Defendant herein breached the aforesaid implied warranty of merchantability because the drug Trulicity was not fit for the drug's intended purposes.

195. Defendant's breaches of implied warranty of merchantability were a substantial factor in causing Plaintiff's injuries.

196. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including ileus, intestinal obstruction, and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

197. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff, for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless

acts of Defendant, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff, in an amount sufficient to punish Defendant and deter future similar conduct;

3. Awarding Plaintiff the costs of these proceedings; and

4. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: December 4, 2023

By: /s/Donald E. Smolen, II

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**Application for admission pro hac vice to be filed*